NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RANDY SMITH, Plaintiff, v. ANTARES PHARMA, INC., *et al.*, Defendants.	Civil Action No. 17-8945 (MAS) (DEA) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court upon Defendants Robert F. Apple, Fred M. Powell, and Leonard S. Jacob's (collectively, "Individual Defendants") and Antares Pharma, Inc.'s ("Antares" or the "Company") Motion to Dismiss. (ECF No. 35.) Lead Plaintiff Serghei Lungu ("Plaintiff") opposed (ECF No. 36), and Individual Defendants and Antares (collectively, "Defendants") replied (ECF No. 37). The Court has carefully considered the parties' arguments and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth herein, Defendants' Motion to Dismiss is granted.

I. BACKGROUND[1]

This matter is a putative securities class action brought "on behalf of . . . all persons other than Defendants who purchased or otherwise acquired Antares common stock between December 21, 2016 and October 12, 2017, both dates inclusive (the 'Class Period') . . . ." (Consolidated Am.

[1] For the purpose of deciding the instant motion, the Court accepts all well-pled factual allegations as true. *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

Compl. ("CAC") ¶ 1, ECF No. 34.)[2] Founded in 1979, "Antares develops, manufactures and commercializes therapeutic products using its drug delivery systems." (*Id.* ¶¶ 2, 3.) The product at issue in this lawsuit—XYOSTED[3]—is an "auto injector product designed for testosterone replacement therapy ('TRT')." (*Id.* ¶ 4.) The gravamen of the CAC is that Antares made "materially false and misleading statements regarding the Company's business, operational and compliance policies[,]" as related to the Federal Drug Administration ("FDA") approval process of XYOSTED. (*Id.* ¶¶ 6-9.)

A. XYOSTED's FDA Approval Process

In July 2014, Antares began a "Phase 3[4] clinical study (QST-13-003) evaluating the efficacy and safety of testosterone enanthate administered once-weekly by subcutaneous injection using the QuickShot auto injector in testosterone deficient adult males."[5] (*Id.* ¶ 69.) QST-13-003 included 150 adult males receiving "a starting dose of 75 mg of QST once weekly for six weeks." (*Id.* ¶ 70.) "On November 3, 2014, Antares announced that the last patient had been enrolled in QST-13-003[,]" and on "February 25, 2015, Antares announced positive top-line

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[2] The instant suit was initiated by Randy Smith on October 23, 2017. (Compl., ECF No. 1.) On July 27, 2018, pursuant to the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4, the Court appointed Plaintiff as Lead Plaintiff and appointed Pomerantz LLP as Lead Counsel. (Order, ECF No. 22.) On August 8, 2018, the parties stipulated, and the Court ordered, that Plaintiff would file an amended complaint. (Order, ECF No. 26.) On October 9, 2018, Plaintiff filed the CAC.

[3] XYOSTED is the brand name for QuickShot Testosterone ("QST"). (CAC ¶ 81.)

[4] A Phase 3 study is one step of the highly regulated process for developing and bringing a new pharmaceutical product to the market in the United States. Specifically, a Phase 3 study is "performed after preliminary evidence suggesting effectiveness of the drug has been obtained . . . ." 21 C.F.R. § 312.21(c). "Phase 3 studies usually include from several hundred to several thousand subjects." (*Id.*)

[5] The CAC provides extensive background information on the new drug approval process. The Court writes primarily for the benefit of the parties and assumes their familiarity with the process. The Court, accordingly, includes only the information required to decide the instant motion.

pharmacokinetic[6] results that showed that the primary endpoint was achieved in the Company's QST-13-003 clinical study." (*Id.* ¶¶ 71-72.) Between July 2014 and February 2015, Antares received written recommendations from the FDA that "the Company create a larger safety database, including approximately 350 [human] subjects exposed to QST with approximately 200 subjects exposed for six months and approximately 100 subjects exposed for a year." (*Id.* ¶¶ 73-74.) In November 2015, Antares submitted the protocol for QST-15-005 to the FDA. (*Id.* ¶ 75.)

In September 2016, Antares announced the results of QST-15-005. (*Id.* ¶ 79.) On November 9, 2016, Apple—Antares's CEO, President, and Director—announced that the Company "had 'completed the clinical portion of the [P]hase 3 work' with respect to QST and was 'targeting a year-end [New Drug Application ("NDA")] submission.'" (*Id.* ¶ 80.) On December 21, 2016, Antares announced that it had submitted an NDA for QST to the FDA. (*Id.* ¶ 119.) On February 27, 2017, Antares announced that the FDA had accepted Antares's NDA for QST. (*Id.* ¶ 122.)

On October 12, 2017, Antares issued a press release stating that it had received correspondence from the FDA "stating that, as part of [the FDA's] ongoing review of the Company's [NDA] for XYOSTED™ (testosterone enanthate) injection, [the FDA had] identified deficiencies that preclude the continuation of the discussion of labeling and postmarketing requirements/commitments at this time." (*Id.* ¶ 157.) The press release further indicated that "[t]he letter does not specify the deficiencies identified by the FDA[,] and there has been no further clarification of the deficiencies by the FDA at this time." (*Id.*) On October 20, 2017, Antares

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[6] "Pharmacokinetics ('PK') refers to the activity of drugs in the body over a period of time, including the processes by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted." (*Id.* at 19 n.11.)

issued a press release stating that it had received a Complete Response Letter ("CRL")[7] from the FDA regarding XYOSTED. (*Id.* ¶ 159.) The press release indicated that the FDA could not approve the QST NDA and had identified "two deficiencies related to clinical data." (*Id.* (emphasis omitted).) Based on QST's clinical trial results, the "FDA [was] concerned that XYOSTED™ could cause a clinically meaningful increase in blood pressure[, and the FDA] . . . raised a concern regarding the occurrence of depression and suicidality." (*Id.* (emphasis omitted).)

On April 5, 2018, Antares announced that the FDA had acknowledged Antares's response to the CRL. (*Id.* ¶ 161.) On October 1, 2018, Antares announced that the FDA had approved XYOSTED with a black box warning.[8] (*Id.* ¶ 162.) The FDA's approval also required a "WARNINGS AND PRECAUTIONS" section. (*Id.* ¶ 163.)

B. What Antares Knew About XYOSTED

FDA Regulatory Pathway 505(b)(2) permits the FDA, and by extension sponsors, to rely upon data developed by parties other than the applicant when approving an NDA. (*Id.* ¶ 50.) The 505(b)(2) process allows sponsors to avoid the expense and time involved with numerous clinical trials and sponsors can receive an expedited review of their NDA. (*Id.* ¶ 53.) The data that the sponsor relies upon must be acceptable to the FDA, and the sponsor must "build a bridge" between the product it is seeking approval for and the available data it is relying upon. (*See id.* ¶ 54.)

Antares developed XYOSTED using the 505(b)(2) regulatory pathway. (*Id.* ¶ 83.) Plaintiff alleges that because of the structure of XYOSTED's clinical trials, a comparison between

[7] The FDA does not make CRLs public at the time they are issued. (CAC ¶ 48.) Thus, the market is dependent on the recipient to publish accurate information regarding a CRL. (*Id.*)

[8] Black box warnings inform consumers and healthcare providers of "serious and sometimes life-threatening adverse drug reactions" and are "the strictest labeling requirements that the FDA can mandate for prescription drugs." (*Id.* ¶ 165.)

XYOSTED and other TRTs "would prove highly relevant with respect to the XYOSTED NDA." (*Id.*)

While developing XYOSTED, Antares was aware that XYOSTED's NDA faced "serious risks in regards to (a) the instance of suicide; and (b) the clinically meaningful increase noted in blood pressure." (*Id.* ¶ 84.) Regarding suicide, no TRT approved by the FDA in the last decade "recorded a case of completed suicide in the treatment arm of any phase's trial." (*Id.* ¶ 86.) Plaintiff alleges that the total number of suicides during XYOSTED's clinical trial was "two or three," instead of the one suicide that was reported to the FDA. (*Id.* ¶ 90 (emphasis omitted).) As to the increase in blood pressure, "XYOSTED's pivotal trial showed a clear tendency towards a high risk of hypertension." (*Id.* ¶ 91.) Specifically, 12.7% of individuals in QST-13-003 and 2.26% of individuals in QST-15-005 experienced hypertension. (*Id.* ¶ 92.) In comparison, in the last six clinical trials for TRTs approved by the FDA, "4.05% of individuals experienced such an adverse event . . . ." (*Id.* ¶ 93.)

Plaintiff relies, in part, on the statements of a Confidential Witness ("CW1"). (*See id.* ¶¶ 98-118.) CW1 was employed by Antares from November 2013 through January 2017 as the Senior Vice President of Pharmaceutical Development. (*Id.* ¶ 98.) He "oversaw the non-clinical aspect of developing Antares's future product pipeline." (*Id.* ¶ 102.) Antares held biweekly[9] meetings that included CW1, Apple, Powell, Jaffe, Steven Knapp, and Rajesh Thaker. (*Id.* ¶ 109.) The clinical trial results for XYOSTED were discussed during these meetings, and Jaffe presented non-finalized clinical study reports. (*Id.* ¶¶ 110-11.) During these meetings, "Jaffe reported that some patients showed an elevation of blood pressure." (*Id.* ¶ 112.) At some point in time during the XYOSTED clinical trials, "there were also updates that two or three suicides occurred and

[9] Plaintiff asserts that the meetings were "usually biweekly," but the Court cannot discern whether Plaintiff means the meetings occurred twice a week or once every two weeks.

were being investigated." (*Id.* ¶ 113 (emphasis omitted).) Per CW1, "Apple and Jaffe[] attempted to justify the adverse events or advance the view that they were not drug related." (*Id.* ¶ 114.) From internal discussions at Antares, CW1 learned of Jacob's reaction to the adverse events. (*See id.* ¶¶ 117-18.)

C. Plaintiff's Claims

Plaintiff brings this putative class action against Defendants asserting two Counts. Count One, brought against all Defendants, alleges that Defendants violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") by, *inter alia*, making a series of materially false and misleading statements. (*Id.* ¶¶ 179-80.) Count Two, brought against Individual Defendants, alleges that pursuant to Section 20(a) of the Exchange Act, Individual Defendants are liable as "controlling persons." (*Id.* ¶¶ 188-93.)

D. Defendants' False and Misleading Statements

Plaintiff alleges that during the Class Period, Defendants made numerous materially false and misleading statements in violation of the Exchange Act. On December 21, 2016, Antares announced the submission of the QST NDA to the FDA through a press release entitled "Antares Pharma Announces Submission of [NDA] for [QST]" (the "December 21 Press Release"). (*Id.* ¶ 119.) On February 27, 2017, Antares announced, via press release, the FDA's acceptance of the QST NDA (the "February 27 Press Release"). (*Id.* ¶ 122.)

On March 14, 2017, during an Antares conference call (the "Q4 2016 Call"), Apple allegedly made several materially false and misleading statements including:

> ***Assuming approval [of QST], that will mean a late 2017 or early 2018 launch. . . . Assuming FDA approval,*** we plan to begin hiring representatives in the fourth quarter of this year in order to successfully launch QST. We've already begun discussions with third[-]party payers to determine pricing and formulary positioning, and key opinion leaders in neurology and endocrinology have expressed enthusiasm for the product ***given the strong PK data and safety profile.*** . . . We believe QST has the opportunity to be a

> first-line therapy for treating testosterone deficiency, ***due to what we believe is potentially best-in-class PK data and patient compliance. We also believe that we can capture share from both the injectable and topical segments of the market, based on our product profile as well as appropriate pricing relative to the market leaders.*** Turning now to slide 11. ***You'll see how impressive the PK data was from the 52-week study.***

(*Id.* ¶¶ 124-25.)[10] During an exchange with an analyst, Apple stated:

> [A] patient will be [potentially available to use] QST very quickly and so – but all of our marketing plans, all of our forecasts internally[,] assume that a patient will have to use a generic – some form of generic testosterone [– before the patient] get[s] to us. But again, I think that we have a very strong value proposition for both the patient and physician with our PK data and the compliance data, and so forth, that we don't anticipate that being a major barrier for us for QST.

(*Id.* ¶ 126 (emphasis omitted).) On the same day as the Q4 2016 Call, Antares filed its Form 10-K (the "2016 10-K") with the Securities Exchange Commission ("SEC"). (*Id.* ¶ 128.)

On April 3, 2017, Antares issued a press release regarding a poster about QST that would be displayed at an industry event (the "April 3 Press Release"). (*Id.* ¶ 133.) The April 3 Press Release discussed QST's clinical trial results and included the following statements:

> According to the investigators, QST was found to be safe, well tolerated and virtually pain free. . . . Serious adverse events [("SAEs")] reported included one case each of worsening depression, vertigo and suicide. All of the [SAEs] were not considered to be related to [QST] by the investigators, however the Company determined that the case of suicide could not be ruled out as potentially being related to [QST].

(*Id.* ¶ 133 (emphasis omitted).)

[10] The CAC contains bold and italic formatting in some, but not all, of the statements that Plaintiff alleges are actionable under the Exchange Act. In instances where the Court recounts allegedly actionable statements with additional language for context, the Court recreates this formatting. In instances where the Court recounts only the allegedly actionable language, the Court omits the bold and italic formatting.

On May 9, 2017, Antares issued a press release entitled "Antares Pharma Reports First Quarter 2017 Operating And Financial Results" (the "May 9 Press Release"). (*Id.* ¶ 136.) On the same day, Antares filed a Form 10-Q with the SEC (the "Q1 2017 10-Q"). (*Id.* ¶ 141.) Also on May 9, 2017, Antares held a conference call (the "Q1 2017 Call"). (*Id.* ¶ 138.) During a portion of the Q1 2017 Call regarding the status of the FDA's review of the XYOSTED NDA, Apple stated that there was "nothing unusual at this point in any regards." (*Id.* ¶ 139 (emphasis omitted).)

On August 8, 2017, Antares held a conference call (the "Q2 2017 Call") during which Apple stated that Antares "will be targeting neurologists, primary care physicians and endocrinologists who are currently high prescribers of testosterone products." (*Id.* ¶ 145 (emphasis omitted).) Apple also stated:

> I think XYOSTED has a lot of benefits for both the patient and physician that – we're not asking the physician to do anything different, we're just – we believe we're just giving them a product that's the best in class. We believe that we're giving them the best way to administer testosterone. . . . So we think that with the home – self-administration at home, painless administration for the patients, steady PK, all those product features bode well for the adoption at the doctor level . . . .

(*Id.* ¶ 148 (emphasis omitted).) In exchanges with two different analysts, Apple stated:

> We believe that even though XYOSTED is, in our opinion, [a] better product[] from – potentially for patients from a compliance and a PK profile and so forth, we intend to actually price it lower than the [other] brands. And the reason is we want to make sure we gain good access for the patients and for the physicians. . . . But we think the net selling price for the company and for the patient will still be a very good value for us and a good value for the patient. . . . I think that our product, we believe, is a first line product. So anyone who is diagnosed with testosterone deficiency, we believe, is the perfect candidate for XYOSTED. . . . So, I think that there isn't any particular patient population that has testosterone deficiency that we're excluding or that we think is a better candidate. . . . And then when they're down for the end of their time, they're typically below the normal range and can feel depressed and really need for a next dose. . . . And we think that – we believe that will benefit the patient as well. So, overall, it's the whole market. Of those 6 million

> prescriptions, we believe that our product is appropriate in both the gel[] and the injectable market.

(*Id.* ¶¶ 150-51.) On the same day as the Q2 2017 Call, Antares filed a Form 10-Q with the SEC (the "Q2 2017 10-Q"). (*Id.* ¶ 153.)

In sum, Plaintiff alleges that Defendants made ten statements[11] that are actionable under the Exchange Act because they were materially false and misleading. Plaintiff alleges that those ten statements were materially false and misleading because, *inter alia*:

> (i) the risk of suicide with XYOSTED was far greater than with any other currently marketed TRT; (ii) multiple suicides had occurred during the QST clinical studies, as opposed to the single instance disclosed to investors; (iii) XYOSTED's pivotal trial showed a clear tendency towards a high risk of hypertension; (iv) Antares had provided insufficient data to the FDA in connection with its NDA for XYOSTED; [and] (v). . . . Antares had overstated the approval prospects for XYOSTED . . . .

(*See id.* ¶¶ 121, 123, 127, 132, 135, 137, 140, 144, 152, 156; *see also id.* ¶¶ 123, 127, 137, 140, 152 (alleging other statements were materially false and misleading for other reasons).) Plaintiff also alleges that the 2016 10-K; the Q1 2017 10-Q; and the Q2 2017 10-Q contained certifications pursuant to the Sarbanes-Oxley Act and the certifications were false. (*Id.* ¶¶ 132, 144, 156.) Plaintiff avers that the same three documents were false because "suicide and hypertension were not merely part of an array of adverse events present among study participants, but were the two most serious adverse events flagged internally" by Antares. (*Id.*)

II. LEGAL STANDARDS

A district court must conduct a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *See Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). The Court must take note of the elements a plaintiff must plead to state a claim;

[11] The ten statements are: (1) the December 21 Press Release; (2) the February 27 Press Release; (3) the Q4 2016 Call; (4) the 2016 10-K; (5) the April 3 Press Release; (6) the May 9 Press Release; (7) the Q1 2017 Call; (8) the Q1 2017 10-Q; (9) the Q2 2017 Call; and (10) the Q2 2017 10-Q.

review the complaint to strike conclusory allegations; and accept as true all of the plaintiff's well-pled factual allegations while "construe[ing] the complaint in the light most favorable to the plaintiff." *Id.*; *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). The Court "must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678).

A. Section 10(b) Claims

Section 10(b) of the Exchange Act makes it "unlawful for any person . . . [t]o use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe . . . ." 15 U.S.C. § 78j(b). The SEC implemented this prohibition by declaring it "unlawful for any person . . . [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading . . . ." 17 C.F.R. § 240.10b-5(b) ("Rule 10b-5"). The Supreme Court has implied a private right of action from the text and purpose of Section 10(b). *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 318 (2007) ("[T]his Court has implied from the statute's text and purpose . . . a right of action to purchasers or sellers of securities injured by its violation.").

To survive a motion to dismiss, a plaintiff bringing an action under Section 10(b) and Rule 10b-5 must plead: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation."

Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37-38 (2011) (quoting *Stoneridge Inv. Partners, LLC v. Sci.-Atl., Inc.*, 552 U.S. 148, 157 (2008)).

B. Pleading Standards

The PSLRA requires plaintiffs bringing Section 10(b) claims "to allege facts giving rise to a 'strong inference' of scienter, which 'must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.'" *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 176 (3d. Cir. 2014) (quoting *Tellabs*, 551 U.S. at 314). This heightened pleading standard alters the Court's analytical approach when considering a Rule 12(b)(6) motion to dismiss. *See Tellabs*, 551 U.S. at 322-24. The first step—"accept[ing] all factual allegations in the complaint as true"—is unchanged from the normal analysis. *Id.* at 322. Next, the Court "must consider the complaint in its entirety" and the usual sources and documents the Court would normally consider. *Id.* At this step, "[t]he inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Id.* at 322-23 (citation omitted) (emphasis in original). At the third step, the Court must "determin[e] whether the pleaded facts give rise to a 'strong' inference of scienter," and "take into account plausible opposing inferences . . . ." *Id.* at 323.

"The strength of an inference cannot be decided in a vacuum." *Id.* Instead, "[t]he inquiry is inherently comparative . . . ." *Id.* The Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. While the inference "need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, ... the inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus[,] strong in light of other explanations." *Id.* (citations omitted).

C. Section 20(a) Claims

To survive a motion to dismiss, a plaintiff bringing an action under Section 20(a) must plead: "(1) an underlying primary violation by a controlled person or entity; (2) that [the defendants] exercised control over the primary violator; and (3) that the [d]efendants, as 'controlling persons,' were in some meaningful sense culpable participants in the fraud." *Wilson v. Bernstock*, 195 F. Supp. 2d 619, 642 (D.N.J. 2002). "Liability under Section 20(a) is predicated upon an independent violation of [the Exchange Act] or the rules or regulations thereunder." *Id.* (internal quotation marks omitted) (quoting *In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 317 (D.N.J. 2001)).

III. DISCUSSION

Defendants move pursuant to Federal Rule of Civil Procedure 12(b)(6) arguing that Plaintiff failed to plead essential elements of both claims. (*See generally* Defs.' Moving Br., ECF No. 35-1.) Defendants argue that Plaintiff's Section 10(b) claim fails because Plaintiff failed to allege: (1) a material misrepresentation or omission; (2) scienter; and (3) loss causation. (*See id.* 10-38.) Defendants further argue that Plaintiff's Section 20(a) claim fails because: (1) Plaintiff has not plead a primary violation of the Exchange Act; (2) Plaintiff has not alleged facts showing that each Defendant was a "controlling person" within the meaning of Exchange Act; and (3) Plaintiff did not plead "culpable participation" by each Defendant. (*Id.* at 39-40.)

Defendants' motion includes 39 exhibits consisting of various SEC filings, press releases, and conference call transcripts. (*See* Exs. 1-39; ECF Nos. 35-3 to 35-41.) Plaintiff argues that two-thirds of the documents Defendants attach to their motion are not cited in the CAC and are not integral to, or explicitly relied upon, by Plaintiff. (Pl.'s Opp'n Br. 18-19, ECF No. 36.) Thus, Plaintiff argues that Defendants are advancing a "factual counter-narrative" that is inappropriate on a motion to dismiss. (*Id.* at 19.)

The parties' briefs also raise an issue regarding whether Plaintiff's allegations about, and based on CW1, are sufficient. Specifically, Defendants argue that the allegations attributed to CW1 are insufficient because the CAC fails to allege when and how CW1 had access to certain information. (Defs.' Moving Br. 28.) Defendants further argue that the allegations in the CAC are insufficient for an inference of scienter to be based on allegations attributed to CW1. (*Id.* at 30.) Plaintiff opposes, arguing that CW1's allegations are sufficiently particularized and meet the PSLRA's pleading standard. (Pl.'s Opp'n Br. 32.)

Because "[t]he PSLRA imposes a particularity requirement on all allegations, whether they are offered in support of a statement's falsity or of a defendant's scienter[,]" the Court must assess CW1's allegations before turning to Defendants' other arguments. *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 263 (3d Cir. 2009). The Court, therefore, first addresses the two threshold issues discussed above and then turns to Defendants' substantive arguments.

A. The Court May Consider a Limited Set of Defendants' Exhibits

When deciding a motion to dismiss, the Court "generally consider[s] only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014). An exception to this general rule is that the Court may consider "a document *integral to or explicitly relied* upon in the complaint," without converting the motion to dismiss into a motion for summary judgment. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (citation omitted) (emphasis in original). The critical question is "whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited." *Schmidt*, 770 F.3d at 249 (citation omitted).

The Court may also consider "items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452

F.3d 256, 260 (3d Cir. 2006) (citation omitted). Items such as SEC filings "are matters of public record of which the court can take judicial notice." *Schmidt*, 770 F.3d at 249. Federal Rule of Evidence 201(b)(2) provides: "The [C]ourt may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." So long as Federal Rule of Evidence 201(b)(2) is satisfied, the Court may take judicial notice of opening and closing stock prices on the New York Stock Exchange. *See Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 600 n.3 (3d Cir. 2000).

Plaintiff argues that the Court should disregard "[E]xhibits 1-9, 11-14, 18, 20-24, 27-30, 35, and 38-39," and that if the Court does consider these exhibits, Defendants' motion should be converted to a summary judgment motion and Plaintiff afforded discovery. (Pl.'s Opp'n Br. 19.) The Court agrees in part and disagrees in part.

Under the current circumstances, Federal Rule of Evidence 201(c)(2) requires the Court to take judicial notice of Exhibits 1-2, 5-9, 11-14, 20-24, 27, 29, 30, and 35 (the "SEC Filing Exhibits") because: (1) they are SEC filings; and (2) Defendants requested that the Court take judicial notice of these filings. (Defs.' Reply Br. 2 n.3 (stating "Defendants hereby request judicial notice of SEC [f]ilings and stock prices."); Fed. R. Evid. 201(c)(2) (stating "the [C]ourt *must* take judicial notice if a party requests and the [C]ourt is supplied with the necessary information.") (emphasis added).) Plaintiff does not argue that the SEC Filing Exhibits are subject to reasonable dispute or question their authenticity. Moreover, the Court finds no basis for a reasonable dispute over the authenticity of the SEC Filing Exhibits. The Court, accordingly, takes judicial notice of the SEC Filing Exhibits.

Exhibits 3, 4, and 28 are Antares press releases dated March 16, 2016; September 22, 2016; and February 27, 2017, respectively, and require deeper analysis. A March 16, 2016 press release is neither integral to, nor relied upon, in the CAC. Plaintiff, on the other hand, relies upon a

September 2016 announcement of the results of QST-15-005 and that information is contained in the September 22, 2016 press release. (*Compare* CAC ¶ 79, *with* Ex. 4, ECF No. 35-6.) Similarly, Plaintiff explicitly relies upon Exhibit 28 because it is the February 27 Press Release containing what Plaintiff alleges to be materially false and misleading statements. (*Compare* CAC ¶ 122, *with* Ex. 28, ECF No. 35-30.) The Court, accordingly, will disregard Exhibit 3, and will consider Exhibits 4 and 28.

Exhibit 18 is purportedly a listing of Antares's historical stock data, sourced from a Yahoo! Finance webpage, that lists Open and Close prices on an approximately daily basis from October 11, 2017 through November 8, 2017. (*See* Ex. 18, ECF No. 35-20.) Plaintiff objects to the Court's consideration of Exhibit 18 because it is unauthenticated and is not cited in, or integral to, the CAC. (Pl.'s Opp'n Br. 20.) Plaintiff argues that Exhibit 18 was submitted for the purpose of injecting new facts contrary to the facts of the CAC. (*Id.*) Defendants argue that the Court can take judicial notice of stock prices because they are not subject to reasonable dispute. (Defs.' Reply Br. 3.)

The Court cannot consider Exhibit 18. As Plaintiff argues, Exhibit 18 is attorney work product, not "a table of historical prices compiled by a reliable financial news service." *In re Intelligroup Sec. Litig.*, 468 F. Supp. 2d 670, 679 (D.N.J. 2006). Thus, Exhibit 18 requires authentication, and it has not been authenticated. *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), as amended (Nov. 20, 2007) ("First, we require that evidence be authenticated before it can be admitted."); Fed. R. Evid. 901(a). The Court notes that the website URL provided by Defendants does not lead directly to a table of stock prices. Instead, the website visitor must enter a date range for the website to return a table. This required manipulation further suggests that Exhibit 18 must be authenticated before the Court may consider it. The Court, therefore, does not consider Exhibit 18.

B. The Court Must Discount Allegations Based on CW1's Statements

"[W]here plaintiffs rely on confidential personal sources but also on other facts, they need not name their sources as long as the latter facts provide an adequate basis for believing that the defendants' statements were false." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 146 (3d Cir. 2004) (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)). The Court evaluates a confidential witness's allegations by considering "detail[s] provided by the confidential source[], the source['s] basis of knowledge, the reliability of the source[], the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *Avaya*, 564 F.3d at 263 (quoting *Chubb*, 394 F.3d at 147). "If anonymous source allegations are found wanting with respect to these criteria, then [the court] must discount them steeply." *Id.* As the Supreme Court stated, "omissions and ambiguities count against inferring scienter, for plaintiffs must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Tellabs*, 551 U.S. at 326 (quoting 15 U.S.C. § 78u-4(b)(2)).

Here, Plaintiff's allegations regarding CW1 are mixed on the *Chubb* test. The source of CW1's knowledge appears to be his personal experience while working at Antares and his attendance at certain meetings during which XYOSTED's clinical trial results were discussed. CW1's knowledge also relies on statements made by others during these meetings because his role was limited to "the non-clinical aspect of developing Antares's future product pipeline." (CAC ¶ 102.)

The Court has a limited basis from which to assess the reliability of CW1's allegations because they are presented to the Court in the CAC as interpreted by counsel, not separately presented in an affidavit, certification, or witness statement. CW1's position at Antares suggests that he would have attended the meetings and been part of the discussions that Plaintiff describes.

Certain portions of CW1's allegations rely on statements made by others. To the extent Plaintiff does not identify the maker of those statements, the Court has very little basis from which to assess the reliability of those statements.

Plaintiff offers corroboration for some of CW1's allegations. Specifically, CW1's allegations regarding discussions of hypertension during the clinical studies are confirmed by Antares's October 12, 2017 press release and the labeling requirements the FDA imposed on XYOSTED. Plaintiff, however, offers no corroboration of CW1's allegation that two or three suicides occurred during the clinical trials. The October 12, 2017 press release and XYOSTED's ultimate labeling requirements do not corroborate the allegations of multiple suicides because they do not identify the number of suicides that occurred during the clinical trials or the number of suicides reported to the FDA. The lack of corroboration of this allegation is stark considering one of Plaintiff's primary themes is that Antares underreported the number of suicides to the FDA and made materially false and misleading statements regarding this topic.

Further undermining Plaintiff's reliance on CW1's statements is the lack of particularity of CW1's allegations. Specifically, CW1 fails to identify the who, what, when, where, and how of some of the sources of his information. *See In re Galena Biopharma, Inc. Sec. Litig.*, 336 F. Supp. 3d 378, 388 (D.N.J. 2018) (stating that plaintiffs must specify "the sources of information with particularity, including the who, what, when, where and how of the sources, as well as the who, what, when, where, and how of the information conveyed by those sources"). While the Court can infer that the meetings CW1 describes occurred between July 2014, the beginning of QST-13-003, and September 2016, the end of QST-15-005, Plaintiff's allegations are ambiguous about when during this 26-month period these discussions occurred. Plaintiff alleges that discussions of the incidents of suicide occurred "early in XYOSTED study," but given the length of said study, this is insufficient. (CAC ¶ 112.)

CW1 and Plaintiff aver that Jaffe "reported that some patients showed an elevation of blood pressure[,]" but that particular allegation stands in contrast to the ambiguous allegation that, at some point in time, there were updates regarding two or three suicides. (*Compare* CAC ¶ 112, *with* CAC ¶¶ 112-3.) CW1 alleges that when adverse incidents were discussed during these executive meetings, Powell and Jaffe participated in these discussions and "attempted to justify the adverse events or advance the view that they were not drug related." (*Id.* ¶ 114.) This allegation is insufficient because it neither states when these discussions were held nor identifies how many of these discussions were held (*e.g.* how often these adverse events were topics of conversation).[12] Because Plaintiff relies on CW1's allegations to show that Defendants' statements were materially false and misleading as well as in support of Plaintiff's scienter allegations, the ambiguity of CW1's allegations is significant in light of the PSLRA's high standard. The Court, therefore, must steeply discount CW1's allegations. *Avaya*, 564 F.3d at 263 n.33 (stating "confidential witness allegations may score highly on the *Chubb* test yet fail either to establish the falsity of a statement, or to give rise to a strong inference of scienter. Nonetheless, for analytical purposes, it is important to distinguish deficiencies relating to the content of allegations from those relating to their form. The *Chubb* test addresses only the latter issue.").

C. Plaintiff Failed to Plead Certain Statements with Particularity

Defendants argue that Plaintiff failed to identify the actionable statements with the requisite specificity. (Defs.' Moving Br. 10-12.) Defendants insist that "rather than identifying *specific* statements, Plaintiff block-quotes vast swaths of public disclosures, . . . and then summarily concludes that 'the statements referenced' were 'false and/or misleading' . . . ." (*Id.* at 11 (internal

[12] As an example of the problems arising from Plaintiff's lack of particularity, if the meetings occurred every two weeks during the 26-month period, then approximately 52 meetings occurred. Plaintiff has failed to identify during which of these 52 meetings these discussions occurred.

citations omitted).) Plaintiff opposes, arguing that because Defendants could "respond to the [CAC's] falsity allegations, in detail, throughout their brief," Defendants "cannot . . . argue that the [CAC] is insufficiently clear as to why their statements are alleged to be false." (Pl.'s Opp'n Br. 22.) Plaintiff avers that he "put Defendants on notice of the Complaint's allegations" and "those allegations [are] sufficient under [Federal Rule of Civil Procedure] 9(b)." (*Id.* at 22-23.) Plaintiff notes that the statements at issue in the CAC "are bolded for emphasis" or identified in the following paragraph. (*Id.* at 23 n.15.) As explained below, the Court agrees with Defendants.

Paragraph 119 of the CAC is preceded by a line that reads "Materially False and Misleading Statements Issued During the Class Period" and is followed by 37 paragraphs detailing 10 statements Plaintiff alleges were materially false and misleading. (*See* CAC ¶¶ 119-57.) While Plaintiff formats portions of certain statements to emphasize particular sentences and phrases (*see e.g.*, *id.* ¶¶ 125, 133, 151), other statements are not similarly formatted (*see e.g.*, *id.* ¶¶ 119, 128, 153).

The PSLRA requires plaintiffs to "specify each statement alleged to have been misleading . . . ." 15 U.S.C. § 78u-4(b)(1)(b). The PSLRA does not explicitly require Plaintiff to adopt the formatting that Plaintiff employed in certain instances, but such formatting greatly assists the Court when it must conduct the required analysis. The lack of such formatting requires the Court to guess which portion, or portions, of the lengthy statements Plaintiff believes to be actionable. For example, the first four sentences of the December 21 Press Release read as follows:

> "The submission of the QST [NDA] represents yet another significant accomplishment for the Company in 2016. It is the first product designed for subcutaneous delivery of testosterone through a fine gauge needle in patients diagnosed with hypogonadism," said Robert F. Apple, President and Chief Executive Officer. "We believe QST could be an excellent treatment option for men with hypogonadism. In addition to virtually eliminating the risk of transference that exists with topical gel products and the uncomfortable deep intramuscular administration associated with

> current injectable therapies, the study data demonstrated that the QuickShot auto injector can provide patients with physiologically normal and steady levels of testosterone over the course of therapy."

(CAC ¶ 119.) Plaintiff failed to indicate whether anything in this portion of the December 21 Press Release is actionable, or whether the statements that follow this passage are the actionable statements. This ambiguity runs afoul of the PSLRA's particularity requirements and inappropriately shifts Plaintiff's burden to the Court. *In re Wilmington Tr. Sec. Litig.*, 852 F. Supp. 2d 477, 490 (D. Del. 2012) ("Until plaintiffs specifically identify the statements on which they would like to proceed and the reasons why these statements are false or misleading, neither the defendants nor the court can address these allegations with the degree of particularity required by the PSLRA.").[13] The CAC's allegations with respect to the following statements do not comply with the PSLRA: the December 21 Press Release, the February 27 Press Release; the 2016 10-K; the May 9 Press Release; the Q1 2017 10-Q; and the Q2 2017 10-Q.

Defendants also argue that Plaintiff failed to plead with particularity in regards to "the reasons why any particular statement was misleading." (Defs.' Moving Br. 11.) Defendants further argue that Plaintiff repeats the "same six phrases[,]" but "fails to tie these conclusions to *specific statements* made by Antares, [and fails to] explain 'the reasons why' those (unidentified) statements were misleading, as required by the PSLRA." (*Id.* at 11-12 (citations omitted).) Plaintiff's Opposition Brief does not address Defendants' contention. The Court agrees with

[13] While Plaintiff argues that his burden has been satisfied because Defendants were able to respond to the CAC, Defendants' ability to file a motion to dismiss does not obviate Plaintiff's obligation to comply with the pleading requirements of the PSLRA, which serve a different purpose than the requirements of Federal Rule of Civil Rule Procedure 9(b). "Private securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law. . . . As a check against abusive litigation by private parties, Congress enacted the [PSLRA]." *Tellabs*, 551 U.S. at 313 (citations omitted).

Defendants and finds that Plaintiff failed to sufficiently plead why the alleged misstatements are actionable.

The PSLRA requires Plaintiff to specify "the reason or reasons why [a] statement is misleading . . . ." 15 U.S.C. § 78u-4(b)(1)(b). After each paragraph identifying the actionable statement, the CAC includes a paragraph repeating the same conclusory statements and adding other conclusions for certain statements. (*See* CAC ¶¶ 121, 123, 127, 132, 135, 137, 140, 144, 152, 156.) Here, Plaintiff's pleading fails because Plaintiff does not relate Defendants' statements to specific reasons why the statements were false or misleading. The CAC is not "puzzle pleading" but it also does not satisfy the PSLRA's particularity requirement by repeating the same five allegations ten times without ever explaining why those allegations, or other allegations, show that the statements were false.

IV. CONCLUSION

For the reasons set forth above, the Court finds that the CAC fails to meet the PSLRA's particularity requirements. Defendants advance several additional arguments regarding scienter, whether the statements are actionable under the Exchange Act, and a lack of loss causation. The Court, however, does not reach the merits of those arguments at this juncture because Plaintiff may be able to address some of the deficiencies in the CAC in an amended complaint. The Court, accordingly, finds good cause to allow Plaintiff to amend the CAC.

An order consistent with this Memorandum Opinion will be entered.

s/Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE